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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,269	02/22/2006	Ryuichi Morishita	ANGES-9	7392
1473	7590	06/24/2008		
ROPEs & GRAY LLP			EXAMINER	
PATENT DOCKETING 39/361			LONG, SCOTT	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/564,269	<b>Applicant(s)</b> MORISHITA ET AL.
	<b>Examiner</b> Scott D. Long	<b>Art Unit</b> 1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 11 April 2008.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 45-50, 52, 55, 58, 59, 61, 62, 64-67, 69-71 and 73-83 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 45-50, 52, 55, 58-59, 61-62, 64-67, 69-71 and 73-83 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 1/9/2006 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No./Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
Paper No./Mail Date \_\_\_\_\_

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_

### **DETAILED ACTION**

*The examiner acknowledges receipt of Applicant's Remarks and Claim amendments, filed on 11 April 2008.*

#### ***Claim Status***

Claims 45-50, 52, 55, 58-59, 61-62, 64-67, 69-71 and 73-83 are pending. Claims 45-50, 52, 55, 58, 59, 61, 62, 64-67, 69-71 and 73-83 are amended. Claims 1-44, 51, 50, 53-54, 56-57, 63, 68, 72 and 84-85 are cancelled. Claims 45-50, 52, 55, 58-59, 61-62, 64-67, 69-71 and 73-83 are under current examination.

#### ***Priority***

This application claims benefit as a 371 of PCT/JP04/09838 (filed 07/09/2004). The application also claims benefit from foreign application PCT/JP2003/08740 (filed 07/09/2003). The instant application has been granted the benefit date, 9 July 2003, from PCT/JP2003/08740.

#### ***Response to Arguments - Claim Objections***

Applicant's arguments (Remarks, page 11) and Claim amendments, filed 11 April 2008, with respect to claims 50, 55, 60, and 71 have been fully considered and are persuasive. The objections of Claims 50, 55, 60, and 71, have been made moot by the claim amendments submitted on 11 April 2008 and are hereby withdrawn.

***Response to Arguments - Claim Rejections 35 USC § 112***

*Response to Arguments – WRITTEN DESCRIPTION (35 USC 112, first paragraph)*

Applicant's arguments, see page 6 and Claim amendments, filed 11 April 2008, with respect to claims 45-52 and 55-85 have been fully considered and are persuasive. The applicant has amended the claims to limit the scope of the claims to NF-kB antisense molecules SEQ ID NO:1, SEQ ID NO:3, and complements thereof. The rejections of Claims 45-52 and 55-85 under 35 USC 112, first paragraph (written description), have been made moot by the claim amendments submitted on 11 April 2008 and are hereby withdrawn.

*Response to Arguments – ENABLEMENT (35 USC 112, first paragraph)*

Applicant's arguments (Remarks, page 12) and Claim amendments, filed 11 April 2008, with respect to the rejection of claims 45-52 and 55-85 under 35 USC 112, 1<sup>st</sup> paragraph (lack of enablement) have been fully considered and they are persuasive. The applicant has amended the claims to limit the scope of the claims to NF-kB antisense molecules SEQ ID NO:1, SEQ ID NO:3, and complements thereof. The rejections of Claims 45-52 and 55-85 under 35 USC 112, first paragraph (lack of enablement), have been made moot by the claim amendments submitted on 11 April 2008 and are hereby withdrawn.

***Response to Arguments - Claim Rejections 35 USC § 102***

The rejection of claims 45-47, 52, 55, and 59 as anticipated over Lee et al., is withdrawn in response to Applicant's amendment or arguments.

Applicant's arguments (Remarks, page 12) and Claim amendments, filed 11 April 2008, with respect to the rejection of claims 45-47, 52, 55, and 59 under 35 USC 102(b) as anticipated by Lee et al. (FASEB Journal, 2001; 15:p.A663, #523.9 [provided in IDS filed 1/9/2006]) have been fully considered and they are persuasive.

The rejections of claims 45-47, 52, 55, and 59 under 35 USC 102(b) as anticipated by Lee et al. have been made moot by the claim amendments submitted on 11 April 2008 and are hereby withdrawn.

***Response to Arguments - Claim Rejections 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

*The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.*

The rejection of claims 45-50, 52, 55, 58-59, 61-62, 64-67, 69-71 and 73-83 remain rejected under 35 USC 103(a) as unpatentable over Lee et al. (FASEB Journal, 2001; 15:p.A663, #523.9 [provided in IDS filed 1/9/2006]) in view of Morishita et al. (US-

6,262,033, issued 17 July 2001) and further in view of Debs et al. (US-5,641,662, issued 24 June 1997) and further in view of Cutie et al. (US-6,464,959, issued 15 October 2002).

Applicant's arguments (Remarks, pages 13-15) and Claim amendments, filed 11 April 2008, with respect to the rejection of claims 45-50, 52, 55, 58-59, 61-62, 64-67, 69-71 and 73-83 under 35 USC 103(a) as unpatentable over Lee et al. in view of Morishita et al. and further in view of Debs et al. and further in view of Cutie et al. have been fully considered but they are unpersuasive.

The applicant argues that none of the references teach a double stranded NF- $\kappa$ B decoy of SEQ DI NO:1 would be useful in treating a respiratory disease (Remarks, page 14, parag.1). The decoy of SEQ ID NO:1, as currently claimed comprises a double stranded oligonucleotide of SEQ ID NO:1 and an oligonucleotide complementary thereto and pharmaceutical additives for a dry powder. Contrary to the applicant's assertion, Morishita et al. teach, not only the single stranded sequence NF- $\kappa$ B decoy, CCTTGAGGGATTCCCTCC, which is 100% identical to SEQ ID NO:1 of the instant application, but also suggests that the oligonucleotides of Morishita can be "double-stranded" (col.2, lines 30-32) and can be formulated in a pharmaceutical composition in "forms such as...powders" (col.3, lines 3-6). Therefore, the examiner finds the applicant's arguments unpersuasive.

The applicant further argues that none of the diseases indicated by Morishita et al. as being an NF- $\kappa$ B associated disease is a respiratory disease. Contrary to the applicant's assertion, Morishita et al. teach that asthma is a disease which is associated

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with NF-kB expression (Morishita et al., col.1, Background Art). Furthermore, Morishita et al. teach ischemic lung disease is affected by activation of genes under the control of NF-kB transcription (Morishita et al., col.1, lines 54-67). Since both the airways (as in the case of asthma) and ischemic lung disease are parts of the "respiratory system" (as indicated in claim 45). Therefore, the examiner finds the applicant's arguments unpersuasive.

The applicant argues that the remaining references do not make up for the deficiencies that Lee and Morishita lack. As described above and in the previous action (11/30/2007), Lee et al. in view of Morishita et al. and further in view of Debs et al. and further in view of Cutie et al. teach all the known elements of the instant claims and it would be obvious to combine them in known ways with no change in their respective functions. Therefore, the examiner finds the applicant's arguments unpersuasive.

Therefore, the examiner hereby maintains the rejection of claims 45-50, 52, 55, 58-59, 61-62, 64-67, 69-71 and 73-83 under 35 USC 103(a) as unpatentable over Lee et al. in view of Morishita et al. and further in view of Debs et al. and further in view of Cutie et al.

***Conclusion***

**THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims are allowed.

***Examiner Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SDL/ Scott Long  
Patent Examiner, Art Unit 1633  
/Janet L. Epps-Ford/  
Primary Examiner, Art Unit 1633